Remarks

35 U.S.C. § 103(a)

The Office rejected claims 1, 6-9, 11-13, and 18-26 as allegedly obvious, under 35 U.S.C. § 103(a). According to the Office, these claims are unpatentable over Villhauer, in view of Luskey because Villhauer teaches the claimed compound of formula IC and Luskey teaches that diabetes and atherosclerosis are co-morbid diseases. Office Action at 3. The Office asserted that it would have been obvious "that the compound of formula IC would be useful to treat hyperlipidemia and atherosclerosis (an associated condition) because it was known that the compound of formula IC is useful in treating type II diabetes, which is known to be a condition comorbid with hyperlipidemia and atherosclerosis. Therefore, by treating the type II diabetes, one is concomitantly treating the hyperlipidemia and atherosclerosis." Office Action at 4.

Applicant respectfully traverses. The compound of formula IC improves the patient's lipid profile above and beyond the improvement that would be expected by treating the patient's diabetes alone. Formula IC, also known as vildagliptin, decreased triglycerides, total cholesterol, and LDL (bad cholesterol) to a greater degree than other drugs that are also used to treat diabetes. These data, presented in more detail below, demonstrate that treating hyperlipidemia and its associated atherosclerosis with the compound of formula IC resulted in a greater therapeutic benefit than would have been expected by one of ordinary skill in the art.

As evidence showing there was no reasonable expectation of success, Applicant submits the abstract by Baron et al. in the concurrently filed Information Disclosure Statement. This abstract reports the results of three clinical trials that compare the effects of vildagliptin with other anti-diabetic drugs in patients with type II diabetes. Vildagliptin improved the fasting lipid profile, decreasing triglycerides by 9.4% and total cholesterol by 13.6%.

If, as the Office contended, treating diabetes concomitantly treats hyperlipidemia, one would expect either no difference between anti-diabetic agents, or that the anti-diabetic effect would correlate with the improvement in lipid profile. This is, however, not the case. Vildagliptin improved the lipid profile to a greater extent than that observed with rosiglitazone or pioglitazone, the latter of which actually worsened the lipid profile. Furthermore, pioglitazone was more effective in lowering the amount of glycosylated hemoglobin (HbA_{1C}), a marker of the effect of elevated blood glucose caused by diabetes, than vildagliptin. Pioglitazone lowered HbA_{1C} by 1.4% and vildagliptin lowered HbA_{1C} by 1.1%, thus the lipid lowering effect of vildagliptin was not due to a more potent anti-diabetic action. One skilled in the art would, therefore, have had no expectation that vildagliptin would result in a superior lipid profile and Applicant requests that the Office withdraw its rejection of claims 1, 6-9, 11-13, and 18-26, under 35 U.S.C. § 103(a).

Double Patenting

The Office provisionally rejected the pending claims on the basis of nonstatutory obviousness-type double patenting. Office Action at 5-9. Applicant requests that the Office hold this rejection in abeyance until claims are granted in one or more of the involved applications.

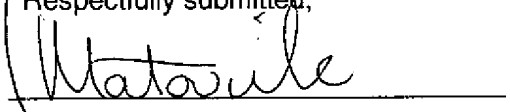
35 U.S.C. § 112

The Office rejected claims 1, 6-9, 11-13, and 18-26, under the first paragraph of 35 U.S.C. § 112. According to the Office, the specification enables the claims with respect to treating hyperlipidemia but not with respect to preventing it. Without acquiescing to the rejection, Applicant herein amends the claims to delete the phrase "preventing." Applicant requests that the Office withdraw its rejection of claims 1, 6-9, 11-13, and 18-26, under 35 U.S.C. § 112.

Conclusion

Applicant submits that the claims are in condition for allowance and requests that the Office issue notice to that effect at its earliest convenience.

Respectfully submitted,



Novartis Pharmaceuticals Corporation
One Health Plaza, Bldg. 101
East Hanover, NJ 07936
(862) 778-5442

Lisa Matovcik
Attorney for Applicant
Reg. No. 53,283

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